REMARKS

By way of the present amendment, Claims 2 and 8-13 are pending. Claims 10-13 are withdrawn. Claims 4-7 have been canceled without prejudice or disclaimer as to the underlying subject matter. Claims 2, 8-10, and 12 have been amended to facilitate prosecution. No new matter has been added by these amendments. Support for the foregoing amendments may be found in the sequence listing, in the original claims and throughout the specification e.g., at page 9, lines 1-6. No new matter is added by the present amendment.

Based on the Advisory Action mailed on December 17, 2008, it is Applicants' understanding that the Examiner did not enter the claim amendments which were presented in the Response to the Final Office Action submitted on November 4, 2008. Accordingly, in this current Response, Applicants have marked-up amended Claims 2, 8-10, and 12 based on the previously examined claim set presented in the Amendment and Response to Office Action submitted on May 14, 2008.

I. Interview Summary

Applicants submit the following summary of the telephonic interview conducted on Tuesday, February 3, 2009. Applicants' representatives thank the Examiner for extending the courtesy of a telephonic interview.

In Attendance:

Examiner: Shubo Zhou

Applicants' representatives: Lisa Adelson and David Vanik

1) Exhibits:

None.

2) Claims Discussed:

All pending claims as submitted on November 4, 2008 were discussed, Claims 2, 4-13.

3) Cited Art Discussed:

Alexandrov *et al.* (EP 1 033 405).

4) Amendments discussed:

Amendments to Claims 2, 4-13 were discussed.

5) Summary of Arguments:

During the telephonic interview, Applicants' representatives respectfully urged the Examiner to consider entering the claim amendments submitted in the November 4, 2008 Response to Final Office Action. The Examiner respectfully disagreed with Applicants' representatives and indicated that he would not consider the proposed after-final claim amendments submitted in the November 4, 2008 Response to Final Office Action. However, the Examiner indicated that the proposed claim amendments would be entered and considered should an RCE be filed. The Examiner also indicated that the remaining utility rejection under 35 U.S.C. § 101 and enablement rejection under 35 U.S.C. § 112, first paragraph, would be revisited

based on the BPAI's recent decision on appeal in U.S. Application No. 10/959,789 should an RCE be filed.

6) Other Matters:

None.

7) General Result:

While no formal final agreement was reached during the interview, Applicants' representatives thank the Examiner for indicating that the claims would be further evaluated in light of the BPAI's recent decision on appeal in U.S. Application No. 10/959,789 should an RCE be filed. Applicants' representatives thank the Examiner for his direction and guidance presented during the telephonic interview.

II. Rejection under 35 U.S.C. § 101

Claims 2 and 4-9 stand rejected under 35 U.S.C. § 101, because allegedly the "claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." Final Action at page 3. In rejecting the claims, the Examiner reiterates the rejections from the Office action mailed February 14, 2008 and further asserts that "[t]he claimed polypeptide is not supported by a specific and substantial asserted utility because none of the uses of the polypeptide as disclosed in the specification such as those detailed on pages 10-18, etc. is specific and substantial." *Id.* Applicants respectfully traverse this rejection.

In *In re Fisher*, the Federal Circuit reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (citing *Brenner v. Manson*, 383 U.S. at 534-35, 1966) (emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*." *Id.* (emphasis in original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

At the outset, Applicants disagree with the Office's assertion that one of skill in the art "would have reasonable doubt that the polypeptide of SEQ ID NO: 44293 would indeed be a "synaptobrevin-like protein." Final Office Action at page 7. In making this assertion, the Office

provides no specific evidence whatsoever that one of skill in the art would have reason to doubt the utility of SEQ ID NO: 44,293 as a synaptobrevin-like protein. Further, Table 1 of the specification discloses that SEQ ID NO: 44,293 exhibits a strong correlation to a synaptobrevin-like protein, gi29150380. Indeed, according to Table 1, SEQ ID NO: 44,293 shares 96% identity with gi29150380. Applicants respectfully submit that this disclosure in Table 1 demonstrates that SEQ ID NO: 44,293 has utilities specific to it and not generally applicable to any amino acid sequence. These utilities are credible, substantial, and well-established; they are neither vague nor impractical. Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case.

Moreover, as set forth in the Response submitted on May 14, 2008, there are numerous utilities asserted in the specification in relation to SEQ ID NO: 44,293. Specification at page 19, line 12 - page 28, line 17 and Table 1. Additionally, the utility of SEQ ID NO: 44,293 is demonstrated by a BLASTP analysis. The specification as filed discloses that a BLASTP analysis is a well-known and conventional technique that can be used to obtain information about nucleic acid sequences. Specification at page 15, line 16 - page 16, line 15. The results of a BLASTP analysis of SEQ ID NO: 44,293, as set forth in the Response submitted on May 14, 2008, show that SEQ ID NO: 44,293 correlates to a synaptobrevin 1 protein found in *Oryza sativa*.

Applicants respectfully disagree with the Office's continued reliance on Everett *et al.* (Nature Genetics 17, 411-422 (1997)) and Scott *et al.* (Nature Genetics 21, 440-443 (1999)) to allegedly show that "assignment of a known function to a metabolic gene based on homology alone provides improper and erroneous functional assignment." Final Office Action at page 6.

Further, the Office does not appear to address Applicants' remarks regarding Everett *et al.* and Scott *et al.* when maintaining the rejections in the September 4, 2008 final Office action. Citing to Everett *et al.* and Scott *et al.*, the Office continues to argue that sequence similarity alone does not correlate to identical or even similar biological activities. *Id.* at page 6. As alleged evidence of this, the Office cites to Scott *et al.* and states that "pendrin, while having 29% homology to the rate sulfate-ion transporter encoded by *Sat*-1; 32% homology to the diastrophic dysplasia sulfate transporter *DTD*; and 45% homology to the human sulfate transporter down-regulated adenoma encoded by *DRA*, is actually not a transporter of sulfate, but rather that of chloride and iodine." *Id.*

Again, as set forth in the May 14, 2008 response, the above-mentioned findings by Scott *et al.* and Everett *et al.* do not in any way suggest that SEQ ID NO: 44,293 lacks utility. For one, Scott *et al.* compares the biological activity of pendrin to sulfate transporters with only 29%, 32%, and 45% structural identity to pendrin. Scott *et al.* at abstract. Everett *et al.* does not remedy the deficiency of Scott *et al.* and compares the biological activity of pendrin to sulfate transporters with only 29%, 31%, 32%, and 45% structural identity to pendrin. Everett *et al.* at Figure 4. Here, SEQ ID NO: 44,293 shares a 96% identity to a synaptobrevin-like protein found in *Oryza sativa*. With this, one of skill in the art would be comfortable that proteins sharing 96% identity would share the same biological function by contrast to proteins sharing 29%, 31%, 32%, or 45% identity.

Moreover, Applicants disagree with the Office's position that the Scott *et al.* and Everett *et al.* references confirm that structural homology is not an accurate predictor of function. Final Office Action at page 6. For one, the Office does not provide any support for the apparent

proposition that a single example of an alleged improper functional assignment based on homology to a known sequence renders homology-based functional assignments unreasonable generally, and in the present case specifically. Further, Scott *et al.* actually confirms that even a very low percentage of structural identity can be indicative of similar biological function. Specifically, according to Scott *et al.*, transporters sharing only 29%, 32%, and 45% structural identity to pendrin still have the ability the ability to act as **anion transporters**. That is, like pendrin, which is a sulfate-anion transporter, transporters sharing only 29%, 32%, and 45% structural identity to pendrin have the ability to transport iodide and chloride, both anions. Scott *et al.* at abstract and Figure 2. However, the Office appears to miss this point in rejecting Applicants' claims.

Applicants further disagree with the Office's assertion that additional evidence must be presented in order to satisfy the utility requirement under 35 U.S.C. § 101. Final Office Action at page 8. For instance, the Office asserts that the sequences which are homologous to SEQ ID NO: 44,293 "appear to have no function in Oryza sativa." Final Office Action at page 8. The Office further asserts that, "[e]ven today, there appears to be no experimental evidence indicating that synaptobrevin 1 is involved in brassinolide signaling in rice." *Id.* The Office's assertion that additional experimental evidence be provided in order to satisfy the utility requirement under 35 U.S.C. § 101 is legally incorrect. Applicants respectfully remind the Office that the utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). As the law provides, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See,*

Fujikawa v. Wattanasin, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added.

The present application provides utilities for the claimed polypeptides that are well-defined and provide an immediate benefit to the public. The fact that the claimed amino acid sequence exhibits a high correlation to a synaptobrevin-like protein is more than ample to support the specific utilities asserted in the specification for SEQ ID NO: 44,293. Additionally, the specification provides that the sequences of the invention can be used for monitoring and modifying synaptobrevin-like protein expression in plants. Specification at page 25, line 6 through page 28, line 17 and Table 1. The specification discloses that nucleic acid sequences encoding the synaptobrevin-like protein can be introduced into a plant cell and transcribed using an appropriate promoter with such transcription resulting in the reduction or suppression of the endogenous synaptobrevin-like protein. Specification at page 19, line 12 through page 28, line 17. The modification of the expression can be monitored, for example, by using an ELISA assay to raise specific antibodies to either a synaptobrevin 1 or synaptobrevin-like protein. Specification at page 25, line 16 through page 26, line 18. Such antibodies can be prepared using the claimed polypeptide sequences. Any <u>one</u> of these asserted utilities is specific, substantial and credible under the requirements of 35 U.S.C. § 101.

Applicants respectfully submit that they have satisfied the utility test set forth in *In re Fisher*. Applicants respectfully submit that SEQ ID NO: 44,293 has specific, substantial, and credible utility because it has a reasonable correlation with a synaptobrevin-like protein, and can be used in a manner that provides some immediate benefit to the public. Therefore, Applicants

respectfully request that the Office reverse the rejection of Claims 2 and 4-9 under 35 U.S.C. § 101.

III. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 2 and 4-9 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled because the claimed invention allegedly lacks utility. Final Office Action at pages 9-10. In rejecting the claims, the Office asserts that the rejection is "reiterated from the previous Office action." *Id.* Applicants respectfully traverse this rejection and submit that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

IV. Claim Rejections under 35 U.S.C. § 102

Claims 2 and 4-9 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Alexandrov *et al.* (EP 1 033 405). Final Office Action at page 10. Applicants respectfully traverse. In rejecting the claims, the Office asserts that the "[i]t is reasonably interpreted that the claim is drawn to a polypeptide comprising any fragment of SEQ ID NO: 44293 that is two or more amino acid residues long." *Id.* at page 11. The Office further asserts that "the reason why the Alexandrov *et al.* reference is again used to reject the claims is that the amendment filed 11/26/07 introduces the limitation 'or a fragment thereof' in the claims." *Id.* at page 12.

In order to facilitate prosecution, Applicants have amended Claims 2, 4-9, 10, and 12 by removing the language "a fragment" from the claims. As such, Applicants respectfully submit that the claim rejections are rendered moot.

In maintaining the rejection, the Office asserts that, "[f]or the claimed sequence SEQ ID NO: 44293, applicant is not entitled to the filing dates of the prior applications as indicated in the Application Data Sheet filed 5/25/07 because the sequence is not found to be disclosed in any of the prior application." *Id.* Applicants disagree. Further, the Office requests that Applicants "indicate which particular SEQ ID NO(s) in those applications that is identical to the instant SEQ ID NO: 44293 if applicant believes the instant application is entitled to the earlier filing dates." *Id.*

Without being limited, support for SEQ ID NO: 44,293 in the captioned application can be found in both U.S. Application No. 09/654,617 (filed September 5, 2000) and U.S. Application No. 09/684,016 (filed October 10, 2000). Specifically, positions 205-864 of the nucleic acid sequence of SEQ ID NO: 271,143 in both U.S. Application No. 09/654,617 and U.S. Application No. 09/684,016 encode the amino acid sequence of SEQ ID NO: 44,293 in the captioned application.[1] As such, the claims are entitled to a priority of at least September 5, 2000, which is earlier than the September 6, 2000 publication date of Alexandrov *et al.*

For all of the foregoing reasons, Applicants respectfully request withdrawal of this

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1 SEQ ID NO: 271,143 contains a total of 1185 bases and the nucleic acid position from 205-864 has the following sequence:

ATGGGGCAGCAGTCGCTGATCTACGCGTTCGTGGCCCGTGGCACGGTCATACTGGCCGAGTACA
CGGAGTTCACCGGCAACTTCACCACCATCGCCTCCCAGTGCCTCATGAAGCTCCCCGCAAGCAA
CAACAAGTTCACCTACAACTGCGACGGTCACACTTTCAATTACCTCGTGGAAGACGGATTCACA
TACTGTGTTGTTGCTGTTGAATCGGTGGGGCAACAAATTCCTATTGCTTTCATGGATAGGGTTAA
GGAGGATTTCACAAAAAGGTATGGTGGTGGGAAAGCTGCTACTGCTGCAGCTAACAGCCTCAAT
CGAGAGTTTGGATCAAAACTTAAAGAACACATGCAGTATTGTGTGGATCACCCTGAAGAGGTTA
GCAAGCTGGCCAAAGTGAAGGCGCAGGTTTCAGAAGTCAAGGGTGTTATGATGGAAAACATTG
AAAAGGTTCTGGATCGTGGAGAGAAGATTGAGCTGCTTGTCGACAAGACCGAGAATCTTCGCTC
ACAGGCACAAGATTTCAGACAGCAGGGAACAAATGTCAGGAGAAAGATGTGGTTACAGAACAT
GAAAATCAAGCTCATCGTCCTGGGAATAATCATCGCACTCATTCTGATCATTATCCTCTCTGTCT
GTCATGGTTTCAAATGCCAT

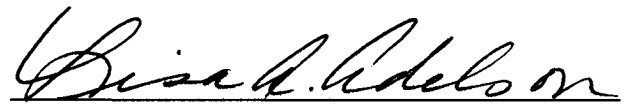
rejection and submit that Alexandrov *et al.* is not prior art against the claims.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5325 if any additional information is necessary for allowance.

Respectfully submitted,

Date: February 4, 2009



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